
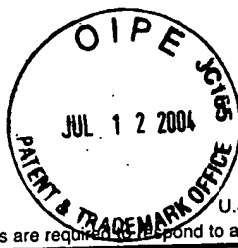


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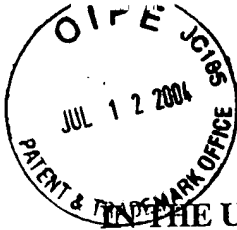
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Date	June 19, 2003

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Date	June 19, 2003



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Scoville and Walke (As Amended)

Serial No.: 09/899,513

Group Art Unit: 1646

Filed: 07/05/2001

Examiner: R. Li

For: Novel Human Membrane Proteins and
Polynucleotides Encoding the Same

Attorney Docket No.: LEX-0200-USA

APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief to the Board of Patent Appeals and Interferences ("the Board") in response to the Final Office Action mailed on January 16, 2003. The Notice of Appeal was timely submitted on April 16, 2003, and was received in the Patent and Trademark Office ("the Office") on April 23, 2003. This Appeal Brief is thus timely submitted. The Commissioner is hereby authorized to charge the fee for filing this Appeal Brief (\$160.00), as required under 37 C.F.R. § 1.17(c), to Lexicon Genetics Incorporated Deposit Account No. 50-0892.

Appellants believe no fees in addition to the fee for filing the Appeal Brief are due in connection with this Appeal Brief. However, should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason related to this communication, the Commissioner is authorized to charge any underpayment or credit any overpayment to Lexicon Genetics Incorporated Deposit Account No. 50-0892.

I. REAL PARTY IN INTEREST

The real party in interest is the Assignee, Lexicon Genetics Incorporated, 8800 Technology Forest Place, The Woodlands, Texas, 77381.

II. RELATED APPEALS AND INTERFERENCES

Appellants know of no related appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

The present application was filed on July 5, 2001, claiming the benefit of U.S. Provisional Application Number 60/217,600, which was filed on July 11, 2000, and included original claims 1-5. A Restriction and Election Requirement was issued on May 22, 2002, separating the original claims into three separate and distinct inventions. In a response to the Restriction and Election Requirement submitted

to the Office on June 24, 2002, Appellants elected without traverse the claim of the Group III invention (original claim 5) for prosecution on the merits, amended claim 5 to further improve its clarity, cancelled claims 1-4 without prejudice and without disclaimer as drawn to non-elected inventions, and added new claims 6 and 7.

A First Official Action on the merits ("the First Action") was issued on July 30, 2002, in which claims 5-7 were rejected under 35 U.S.C. § 101 as allegedly lacking a patentable utility, claims 5-7 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility, and claim 5 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In a response to the First Official Action submitted to the Office on December 2, 2002 ("Response to the First Action"), Appellants amended claim 5 to even further improve its clarity, and addressed the rejections of claims 5-7.

A Second and Final Official Action ("the Final Action") was mailed on January 16, 2003, indicating that the rejection of claim 5 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite was overcome by Appellants remarks and amendment, but maintaining the rejection of claims 5-7 under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility. In a response to the Second and Final Office Action submitted on March 17, 2003 ("Response to the Final Action"), Appellants again addressed the rejections of claims 5-7. An Advisory Action ("the Advisory Action") was mailed on April 23, 2003, maintaining the rejection of claims 5-7 under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility. Therefore, claims 5-7 are the subject of this appeal. A copy of the appealed claims are included below in the Appendix (Section IX).

IV. STATUS OF THE AMENDMENTS

As no amendments subsequent to the Final Action have been filed, Appellants believe that no outstanding amendments exist.

V. SUMMARY OF THE INVENTION

The present invention relates to Appellants' discovery and identification of novel human polynucleotide sequences that encode a novel ligand binding protein (specification at page 2, lines 5-7).

The presently claimed polynucleotide sequences were compiled from clustered human gene trapped sequences, genomic sequences, ESTs, and cDNAs generated from human testis, skeletal muscle, mammary gland and lymph node mRNAs (specification at page 17, lines 4-6).

The specification details a number of uses for the presently claimed polynucleotide sequences, including in assessing gene expression patterns, particularly using a high throughput "chip" format (see, for example, the specification at page 6, lines 15-17), and in mapping the sequences to a specific region of a human chromosome (see, for example, the specification at page 3, line 8).

VI. ISSUES ON APPEAL

1. Do claims 5-7 lack a patentable utility?
2. Are claims 5-7 unusable by a skilled artisan due to a lack of patentable utility?

VII. GROUPING OF THE CLAIMS

For the purposes of the outstanding rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, the claims will stand or fall together.

VIII. ARGUMENT

A. Do Claims 5-7 Lack a Patentable Utility?

The Final Action first rejects claims 5-7 under 35 U.S.C. § 101, as allegedly lacking a patentable utility due to not being supported by either a specific and substantial or a well-established utility.

Appellants point out that a sequence that has over 99% identity at the protein level with the claimed sequence is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by third party scientists *wholly unaffiliated with Appellants* as a "G-protein coupled receptor" (GenBank accession number AX647175, corresponding to European Patent Application

Number EP 1270724; alignment and front page from EP 1270724 shown in **Exhibit A**). The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given this GenBank annotation, there can be no question that those skilled in the art would clearly believe that Appellants' sequence is a G-protein coupled receptor (GPCR).

The Final Action and the Advisory Action question prediction of protein function based upon protein homology. In support of this allegation, articles by Bork and Koonin (1998, *Nature Genetics* 18:313-318; "Bork and Koonin"), Ji *et al.* (1998, *J. Biol. Chem.* 273:17299-17302; "Ji") and Yan *et al.* (2000, *Science* 290:523-527; "Yan") are cited. Appellants will first set forth the shortcomings of these particular articles, and then point out the failure of these articles to support the alleged lack of utility of the presently claimed sequence.

First, with regard to the Bork and Koonin article, Bork and Koonin themselves conclude "(i)n summary, the currently available methods for sequence analysis are sophisticated, and while further improvements will certainly ensue, they are already capable of extracting subtle but functionally relevant signals from protein sequences (Bork and Koonin, page 317). Thus, the Bork and Koonin article is hardly indicative of a high level of uncertainty in assigning function based on sequence, and thus does not support the alleged lack of utility.

With regard to Ji, an exact quote from Ji completely undermines the question of asserted utility based upon protein homology: "a substantial degree of amino acid homology is found between members of a particular subfamily, but comparisons between subfamilies show significantly less or no similarity" (Ji at 17299, first paragraph, emphasis added). This quote suggests that homology with members of a G-protein coupled receptor is indicative that the particular sequence is in fact a member of that subfamily - the fact that there is little or no homology between subfamilies is completely irrelevant. Thus, Ji does not support the alleged lack of utility.

Furthermore, regarding Yan, this paper cites only one example, two isoforms of the anhidrotic ectodermal dysplasia (EDA) gene, where a two amino acid change conforms one isoform (EDA-A1) into the second isoform (EDA-A2). However, while it is true that this amino acid change results in binding to

different receptors, it is important to note that the different receptors bound by the two isoforms are in fact related (Yan at page 523). Furthermore, the EDA-A2 receptor was correctly identified as a member of the tumor necrosis factor receptor superfamily based solely on sequence similarity (Yan at page 523). Thus, Yan does not suggest a high level of uncertainty in assigning function based on sequence, and thus also does not support the alleged lack of utility.

Furthermore, with regard to the citation of journal articles to support an allegation of a lack of utility, the PTO has repeatedly attempted to deny the utility of nucleic acid sequences based on a small number of spurious publications that call into doubt the usefulness of bioinformatic predictions, of which these three articles are merely the latest examples. However, Appellants point out that the lack of 100% unanimous agreement on the usefulness of bioinformatic prediction programs is completely irrelevant to the question of whether the claimed nucleic acid sequence has a substantial and specific utility. Appellants respectfully point out that, as discussed above, the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be believable. Appellants submit that the overwhelming majority of those of skill in the relevant art would believe bioinformatic prediction to be a powerful and useful tool, as evidenced by hundreds if not thousands of journal articles, and would thus believe that Appellants sequence is a GPCR. As believability is the standard for meeting the utility requirement of 35 U.S.C. § 101, and not unanimous consent, Appellants submit that the present claims must clearly meet the requirements of 35 U.S.C. § 101.

Rather, with regard to the utility of the presently claimed sequence, as 60% of the pharmaceutical products currently being market by the entire industry target G-protein coupled receptors (Gurrath, 2001, Curr. Med. Chem. 8:1605-1648; abstract presented in **Exhibit B**), a preponderance of the evidence clearly weighs in favor of Appellants' assertion that the skilled artisan would readily recognize that the presently described sequences have a specific (the claimed GPCR proteins are encoded by a specific locus on the human genome, see below), credible, and well-established utility, for example in tracking gene expression, as described in the specification as originally filed, at least at page 6, lines 15-17. In particular, the specification describes how the described sequences can be represented using a gene chip format to provide a high throughput analysis of the level of gene expression. Such "DNA chips" clearly have utility,

as evidenced by hundreds of issued U.S. Patents, as exemplified by U.S. Patent Nos. 5,445,934 (Exhibit C), 5,556,752 (Exhibit D), 5,744,305 (Exhibit E), 5,837,832 (Exhibit F), 6,156,501 (Exhibit G) and 6,261,776 (Exhibit H). Evidence of the "real world" substantial utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies that have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, one such company (Rosetta Inpharmatics) was viewed to have such "real world" value that it was acquired by large a pharmaceutical company (Merck) for significant sums of money (net equity value of the transaction was \$620 million). The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well established. Clearly, there can be no doubt that the skilled artisan would know how to use the presently claimed sequences (see Section VIII(B), below), strongly arguing that the claimed sequences have utility. Given the widespread utility of such "gene chip" methods using *public domain* gene sequence information, there can be little doubt that the use of the presently described *novel* sequences would have great utility in such DNA chip applications. As the present sequences are specific markers of the human genome (see below), and such specific markers are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequences would be ideal, novel candidates for assessing gene expression using such DNA chips. Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Final Action questioned this utility, stating "(s)ince the disclosure does not reveal any activity/functions of the nucleotide sequence or the protein encoded by the nucleotide sequence, one skilled in the art would not know how to use the claimed invention" (the Final Action at page 6). However, this argument is thwarted by the fact that skilled artisans already have used and continue to use sequences such as Appellants in gene chip applications. Appellants respectfully point out that this is exactly how most gene

chip applications are carried out. Expression profiling does not require a knowledge of the function of the particular nucleic acid on the chip - rather the gene chip indicates which DNA fragments are expressed at greater or lesser levels in two or more particular tissue types. Therefore, this argument also fails to support the alleged lack of utility of the presently claimed compositions.

Clearly, persons of skill in the art, as well as venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. Billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, e.g., Venter *et al.*, 2001, Science 291:1304; **Exhibit I**). The results have been a stunning success as the utility of human genomic data has been widely recognized as a great gift to humanity (see, e.g., Jasny and Kennedy, 2001, Science 291:1153; **Exhibit J**). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years).

It is important to remember that the requirement for a specific utility, which is the proper standard under 35 U.S.C. § 101, should not be confused with the requirement for a unique utility, which is clearly an improper standard. The fact that other expressed sequences can be used to track gene expression on a DNA chip does not mean that the use of Appellants' sequence to track gene expression on a gene chip is not a specific utility. As clearly stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991):

An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, just to name a few particular examples, because examples of each of these have already been described and patented. However, only the briefest perusal of any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Furthermore,

if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

Although Appellants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), as yet a further example of the utility of the presently claimed polynucleotides, as described in the specification at least at page 3, line 8, the present nucleotide sequence has a specific utility in mapping the sequences to a specific region of a human chromosome. This is evidenced by the fact that SEQ ID NO:1 can be used to map the presently claimed sequence to chromosome 1 (present within the chromosome 1 clone, Genbank Accession Number AC114490; alignment and the first page from the Genbank report are presented in **Exhibit K**). Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 1 that contains the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequences. In fact, it is this specificity that makes this particular sequence so useful. Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human genome, such as the present nucleic acid sequence. For further evidence in support of the Appellants' position, the Board is requested to review, for example, section 3 of Venter *et al.* (*supra* at pp. 1317-1321, including Fig. 11 at pp.1324-1325; **Exhibit I**), which demonstrates the significance of expressed sequence information in the structural analysis of genomic data. The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome essentially as described in the Venter *et al.* article. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Appellants respectfully remind the Board that only a minor percentage of the genome (2-4%)

actually encodes exons, which in-turn encode amino acid sequences. The presently claimed polynucleotide sequence provides biologically validated empirical data (e.g., showing which sequences are transcribed and polyadenylated) that *specifically* define that portion of the corresponding genomic locus that actually encodes exon sequence. Appellants respectfully submit that the practical scientific value of expressed and polyadenylated mRNA sequences is readily apparent to those skilled in the relevant biological and biochemical arts. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

It has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974; “*Langer*”); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). As clearly set forth in *Langer*:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, “Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered ‘false’ by a person of ordinary skill in the art” (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Regarding the utility requirements under 35 U.S.C. § 101, the Federal Circuit has clearly stated “(t)he threshold of utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip Inc. v. Orange Bang Inc.*, 185 F.3d 1364, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that “(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result,” *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); “*Cross*”) states “any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101”. *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that “anything under the sun that is made by man” is patentable (*State Street Bank & Trust Co. v. Signature Financial Group Inc.*,

149 F.3d 1368, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (U.S., 1980)). Thus, based on the relevant case law, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Final Action also questions the applicability of this case law, stating that "the Response cites a device case law" and "(t)hus, applicants' argument citing a case law regarding a device is irrelevant to the instant case" (the Final Action at pages 4 and 5). Section 101 of the Patent Act of 1952, 35 U.S.C. § 101, provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery. Appellants point out that 35 U.S.C. § 101 covers devices (machine) as well as compositions, and makes no distinction between the two with regard to meeting the burden of complying with 35 U.S.C. § 101. Furthermore, the case law in question (*Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999)) cites *Brenner v. Manson*, 383 U.S. 519, 534 (1966), which the Examiner obviously believes is not "irrelevant to the instant case", since the Examiner himself cites this exact case three times in the Final Action (see the Final Action at pages 4, 5 and 6). Additionally, *Cross and Diamond vs. Chakrabarty*, *supra*, do not concern devices, but rather compositions. Thus, this argument completely fails to support the alleged lack of utility of the presently claimed compositions.

Further, in *In re Brana* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the Patent and Trademark Office for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C.

§§ 101 and 112, first paragraph. The Federal Circuit concluded:

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted, emphasis added. Even if, *arguendo*, further research might be required in certain aspects of the present invention, this does not preclude a finding that the invention has utility, as set forth by the Federal Circuit's holding in *Brana*, which clearly states, as highlighted in the quote above, that "pharmaceutical inventions, necessarily includes the expectation of further research and development" (*Brana* at 1442-1443, emphasis added). In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Finally, While Appellants are well aware of the new Utility Guidelines set forth by the USPTO, Appellants respectfully point out that the current rules and regulations regarding the examination of patent applications is and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Appellants are unaware of any significant recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous

patents that have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines. As examples of such issued U.S. Patents, the Board is invited to review U.S. Patent Nos. 5,817,479 (**Exhibit L**), 5,654,173 (**Exhibit M**), and 5,552,281 (**Exhibit N**; each of which claims short polynucleotides), and recently issued U.S. Patent No. 6,340,583 (**Exhibit O**; which includes no working examples), none of which contain examples of the “real-world” utilities that the Examiner seems to be requiring. Additionally, the Office has recently issued U.S. Patent 6,043,052 (**Exhibit P**), which concerns an “orphan” G-Protein coupled receptor identified based only on homology to the orphan receptor GPR25, similar to the situation with Appellants’ currently claimed sequence. Importantly, this issued patent also contains no examples of the “real world” utilities seemingly required in the present case. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section VIII(B), below), Appellants submit that the present polynucleotides must also meet the requirements of 35 U.S.C. § 101. While Appellants understand that each application is examined on its own merits, Appellants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. Thus, holding Appellants to a different standard of utility would be arbitrary and capricious, and, like other clear violations of due process, cannot stand.

For each of the foregoing reasons, Appellants submit that the rejection of claims 5-7 under 35 U.S.C. § 101 must be overruled.

B. Are Claims 5-7 Unusable Due to a Lack of Patentable Utility?

The Final Action next rejects claims 5-7 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by either a clear asserted utility or a well-established utility.

The arguments detailed above in Section VIII(A) concerning the utility of the presently claimed sequences are incorporated herein by reference. As the Federal Circuit and its predecessor have

determined that the utility requirement of Section 101 and the how to use requirement of Section 112, first paragraph, have the same basis, specifically the disclosure of a credible utility (*In re Brana, supra*; *In re Jolles*, 628 F.2d 1322, 1326 n.11, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971)), Appellants submit that as claims 5-7 have been shown to have "a specific, substantial, and credible utility", as detailed in Section VIII(A) above, the present rejection of claims 5-7 under 35 U.S.C. § 112, first paragraph, cannot stand.

Appellants therefore submit that the rejection of claims 5-7 under 35 U.S.C. § 112, first paragraph, must be overruled.

IX. APPENDIX

The claims involved in this appeal are as follows:

5. (Twice Amended) An isolated nucleic acid expression vector comprising a nucleotide sequence that:

- (a) encodes the amino acid sequence shown in SEQ ID NO: 2; and
- (b) hybridizes to the nucleotide sequence of SEQ ID NO:1 or the complement thereof under highly stringent conditions of 0.5 M NaHPO₄, 7% sodium dodecyl sulfate (SDS) and 1 mM EDTA at 65°C and washing in 0.1x SSC/0.1% SDS at 68°C.

6. An isolated nucleic acid expression vector comprising the nucleotide sequence of SEQ ID NO:1.

7. A host cell comprising the expression vector of claim 6.

X. CONCLUSION

Appellants respectfully submit that, in light of the foregoing arguments, the Final Action's conclusion that claims 5-7 lack a patentable utility and are unusable by the skilled artisan due to a lack of patentable utility is unwarranted. It is therefore requested that the Board overturn the Final Action's rejections.

Respectfully submitted,

June 19, 2003

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